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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/030,832	02/26/1998	MICHAEL C. HANNA	1488.0950001	7860

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HUMAN GENOME SCIENCES INC  
INTELLECTUAL PROPERTY DEPT.  
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ROCKVILLE, MD 20850

EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/030,832

Applicant(s)

HANNA ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on the Amendment dated 1/23/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 95-147 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 98-106 and 136-144 is/are allowed.
- 6) ☒ Claim(s) 95-97, 107-135 and 145-147 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Prosecution of this Application was suspended in the Paper mailed by the Office 10/22/02. However, upon further consideration by the Examiner, new issues have been raised. Therefore, the Finality of the Office Action mailed 6/4/01 has been withdrawn and prosecution on the merits continues.

#### **1. Formal Matters**

- A. The Amendment dated 1/23/02 has been entered into the record.
- B. The Amendment dated 11/30/01 has been entered into the record.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

#### **2. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement**

- A. Claims 95-97, 107-114, 127-135 and 145-147 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptide of SEQ ID NO:42, and those at least 95% identical, does not reasonably provide enablement for partial sequences of SEQ ID NO:42 (**residues 1-260**), for polypeptides which **hybridize** to SEQ ID NO:41, or for host cells which are not “**isolated**.” The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to Applicants claiming polynucleotides encoding GABA receptors which are at least 95% identical to amino acids 1-260 of SEQ ID NO:42. The claims do recite that the subunit of SEQ ID NO:42 must form a complex with  $\alpha$ - and  $\beta$ - GABA subunits and allows for a current. While these functional limitations, themselves, are acceptable, the issue is with regard to Applicants claiming a functional GABA subunit of less than the full-length GABA subunit of SEQ ID NO:42. Applicants have not demonstrated that a subunit less than residues 1-488 of SEQ ID

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NO:42 has the claimed functions, nor have Applicants demonstrated that a polypeptide 95% identical to residues 1-260 would, similarly, have the desired function. Applicants have not provided any guidance or working examples of polypeptides which comprise residues 1-260 of SEQ ID NO:42 or which are 95% identical 1-260. Applicants have not taught which residues are critical for protein function and, therefore, which could be altered. The issue is similar to that regarding "hybridization" language – Applicants have not taught how to structurally identify a GABA subunit which hybridizes to SEQ ID NO:41 which is not SEQ ID NO:41. Due to this lack of guidance and working examples, it is not predictable to the artisan how to make a functional GABA receptor subunit other than that of SEQ ID NO:42.

Furthermore, Applicants have not provided any guidance or working examples of using any host cells other than those which have been isolated. The recitation of non-isolated host cells in the claims raises the issue of using the polynucleotide and/or polypeptides in methods of gene therapy for which Applicants are not enabled.

In summary, the breadth of the claims is excessive with regard to Applicants claiming all polynucleotides encoding polypeptides which encode residues 1-260 of SEQ ID NO:42, which are at least 95% identical to residues 1-260, or which hybridize to SEQ ID NO:41. Applicants have not provided any guidance or working examples of these polynucleotide or polypeptides, nor is it predictable to the artisan how to make a functional GABA receptor subunit other than that of SEQ ID NO:42. For these reasons, the Examiner holds that undue experimentation is required to practice the invention as claimed.

### ***3. Claim Rejections - 35 USC § 112, first paragraph – written description***

A. Furthermore, Applicants have not provided any guidance or working examples of any "mature" GABA subunit other than residues 1-488 of SEQ ID NO:42. Applicants have not taught what residues are altered in any mature form, nor, respectfully, for that reason any GABA subunit other than that of the full-length protein of SEQ ID NO:42. The instant specification fails to describe that portion of a protein which is the "mature" portion. Applicant is claiming a very specific species which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The structure of a "mature" polypeptide cannot be predicted on the basis of the amino acid sequence of the entire protein since the protein may be proteolytically cleaved in vivo, as well as being differentially processed based on which in tissue the protein is expressed. The claims are directed to a species of protein, the structure of which cannot be determined or predicted from full-length amino acid sequence and the specification does not

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evidence isolation or conception of the structure of the "mature" form. Therefore, the specification does not provide an adequate written description of a mature protein, and thus the claimed invention, to the extent that it reads upon mature protein was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

#### **4. Conclusion**

A. Claims 98-106 and 136-144 are allowable.

#### ***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 10 AM – 7 PM (eastern); alt F 10 AM – 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Landsman  
Primary Examiner  
Art Unit 1647

  
ROBERT S. LANDSMAN, PH.D.  
PRIMARY EXAMINER